Robust Summaries of Existing Data

PHYSICO-CHEMICAL PROPERTY – OCTANOL/WATER PARTITION COEFFICIENT	
Test Substance	
Chemical Name	Pentaerythritol Ester of Rosin
CAS #	8050-26-8
Method	
Method/Guideline followed	Testing was conducted according to OECD Test Method 117, "Partition Coefficient (n-Octanol/Water) High Performance Liquid Chromatograph (HPLC) Method."
Test Type	Partition coefficient
GLP (Y/N)	Y
Year (Study Performed)	1993
Test conditions	Pentaerythritol ester of rosin was dissolved in methanol and the solution was analyzed by HPLC with UV detection using a mobile phase of methanol:buffer (3:1) at pH 2 and pH 7.5. As a reference substance, a mixture of seven materials was used.
Results	At pH 2, the log P_{ow} values of two components in pentaerythritol ester of rosin were 6.1 and 7.1. At pH 7.5, the log P_{ow} value of one component in pentaerythritol ester of rosin was 3.6.
Data Quality	Reliable without restrictions – Klimisch Code 1a
References	Dybdahl, H.P. 1993. Determination of log Pow for single components in pentaerythritol ester of rosin. GLP Study No. 408335/477. Water Quality Institute, Horsholm, Denmark.

PHYSICO-CHEMICAL PROPERTY – OCTANOL/WATER PARTITION COEFFICIENT	
Test Substance	
Chemical Name	Glycerol Ester of Rosin
CAS #	8050-31-5
Method	
Method/Guideline followed	Testing was conducted according to OECD Test Method 117, "Partition Coefficient (n-Octanol/Water) High Performance Liquid Chromatograph (HPLC) Method."
Test Type	Partition coefficient
GLP (Y/N)	Y
Year (Study Performed)	1993
Test conditions	Glyercol ester of rosin was dissolved in methanol and the solution was analyzed by HPLC with UV detection using a mobile phase of methanol:buffer (3:1) at pH 2 and pH 7.5. As a reference substance, a mixture of seven materials was used.
Results	At pH 2, no log P_{ow} values in glycerol ester of rosin were detected. At pH 7.5, no log P_{ow} values in glycerol ester of rosin were detected.
Data Quality	Reliable without restrictions – Klimisch Code 1a
References	Dybdahl, H.P. 1993. Determination of log Pow for single substances in glycerol ester of rosin. GLP Study No. 408335/478. Water Quality Institute, Horsholm, Denmark.

ENVIRONMENTAL FATE – BIODEGRADATION	
Test Substance	
Chemical Name	Methyl ester of partially hydrogenated rosin
CAS #	8050-15-5
Method	
Method/Guideline followed	Testing was conducted according to OECD Guideline 301B, "Ready Biodegradability: Modified Sturm Test."
Test Type (aerobic/anaerobic)	Aerobic
GLP (Y/N)	Y
Year (Study Performed)	1988
Contact time	28 days
Inoculum	Activated sludge from the Schijndel municipal sewage treatment plant
Test conditions	Inoculum: Activated sludge microorganisms were obtained from the Schijndel municipal sewage treatment plant at Schijndel. Concentration of test chemical: The test material was used at concentrations of 10 and 20 mg/L. Test Setup: Nutrient solution was prepared in bottles by adding a potassium phosphate, magnesium sulfate, calcium chloride, and ferric chloride, and ammonia sulfate solutions as per the OECD test method. To the nutrient solution was added 30 mL of inoculum; the media was aerated with CO_2-free air for 20 hours. After this, three wash bottles per test bottle were filled with 80 mL of barium hydroxide and connected in series to the exit air line of each test bottle. On day 0 of the study, the test material was added to provide final concentrations of 10 and 20 mg/L and positive control (sodium acetate) was added to one test bottle at a concentration of 20 mg/L. One test bottle without test or control substances was used as a blank. The media was agitated continuously. CO_2 was captured by reaction in the barium hydroxide bottles. The temperature ranged from 18.5 to 20^{o}C. Sampling frequency: Samples were collected from the first CO_2 absorber vessel on days 2, 5, 7, 9, 12, 14, 16, 21, and 28. Controls: Yes. Analysis: The amount of CO_2 produced was determined by titrating the remaining barium hydroxide in the CO_2 absorber bottles with 0.05 N HCl. Carbon content was determined using a C-absorption apparatus.

Results	
Degradation % after time	17.7 and 28.3% after 28 days (test article at low and high concentrations, respectively); 95.6% after 28 days (sodium benzoate)
Conclusions	The low concentration of the test article was degraded 17.7% after 28 days and the high concentration was degraded 28.3%. Sodium benzoate was degraded 95.6% after 28 days. Under the conditions of the OECD guidelines, the test article cannot be considered to be readily biodegradable.
Data Quality	Reliable without restrictions– Klimisch Code 1a
References	Bogers, M. 1988. Biodegradability study of [trade name deleted; methyl ester of partially hydrogenated rosin] in the modified Sturm test. Study Ref. No. 1065/ST36. RCC NOTOX, The Netherlands.

ACUTE TOXICITY – ORAL	
Test substance	
Chemical Name	Methyl ester of partially hydrogenated rosin
CAS #	8050-15-5
Method	
Method/Guideline followed	Testing was conducted according to OECD Guideline 401, "Acute Oral Toxicity."
GLP (Y/N)	Y
Year (Study Performed)	1988
Species	Rat
Strain	Wistar
Route of administration	Oral
Dose levels	2,000 mg/kg
Sex and number/group	5 male and 5 female rats
Frequency of treatment	Single oral gavage
Duration of test	14 day observation post-treatment
Control group (Y/N)	N
Result	
Acute Oral LD_{50}	>2,000 mg/kg
Detailed Summary	Wistar rats (n = 5/sex) received a single oral (gavage) dose of 2,000 mg/kg of the methyl ester of partially hydrogenated rosin (CAS #8050-15-5) and were observed for 14 days. Parameters evaluated included clinical observations, mortality, body weight, and gross pathology. No deaths occurred and no adverse clinical signs were noted. All animals gained weight during the study. Gross pathology revealed no treatment-related effects. The LD_{50} was greater than 2,000 mg/kg.
Data Quality	Valid without restriction – Klimisch Code 1a
Reference	Daamen, P.A.M. 1988. Acute oral toxicity of [trade name deleted; methyl ester of partially hydrogenated rosin] in the rat. Study No. 1065/1426. RCC NOTOX, The Netherlands.

ACUTE TOXICITY – ORAL	
Test substance	
Chemical Name	Methyl ester of partially hydrogenated rosin
CAS #	8050-15-5
Method	
Method/Guideline followed	Testing was conducted according to OECD Guideline 401, "Acute Oral Toxicity."
GLP (Y/N)	Y
Year (Study Performed)	1990
Species	Rat
Strain	Wistar
Route of administration	Oral
Dose levels	2,000 mg/kg
Sex and number/group	5 male and 5 female rats
Frequency of treatment	Single oral gavage
Duration of test	14 day observation post-treatment
Control group (Y/N)	N
Result	
Acute Oral LD_{50}	>2,000 mg/kg
Detailed Summary	Wistar rats (n = 5/sex) received a single oral (gavage) dose of 2,000 mg/kg of the methyl ester of partially hydrogenated rosin (CAS #8050-15-5) and were observed for 14 days. Parameters evaluated included clinical observations, mortality, body weight, and gross pathology. No deaths occurred and no adverse clinical signs were noted. All animals gained weight during the study. Gross pathology revealed no treatment-related effects. The LD_{50} was greater than 2,000 mg/kg.
Data Quality	Valid without restriction – Klimisch Code 1a
Reference	Riebeek, W.M. 1990. Determination of the acute oral toxicity of [trade name deleted; methyl ester of partially hydrogenated rosin] in rats. Report No. V 90.203. TNO-CIVO Institutes, The Netherlands.

ACUTE TOXICITY – ORAL	
Test substance	
Chemical Name	Methyl ester of rosin
CAS #	68186-14-1
Method	
Method/Guideline followed	Testing was similar to OECD Guideline 401, "Acute Oral Toxicity," except no body weight or clinical observation data were collected.
GLP (Y/N)	N (pre-GLP)
Year (Study Performed)	1932
Species	Rat, Guinea Pig, Rabbit
Strain	Not specified
Route of administration	Oral
Dose levels	8,000 to 80,000 mg/kg
Sex and number/group	1 to 3 rats/dose, 1 to 6 guinea pigs/dose, 1 to 3 rabbits/dose; sex not specified for any species
Frequency of treatment	Single oral gavage
Duration of test	10 day observation post-treatment
Control group (Y/N)	N
Result	
Acute Oral LD_{50}	Not identified
Detailed Summary	All species tested received single oral gavage doses of methyl ester of rosin (CAS #68186-14-1). Rats (n = 1 to 3/dose) received doses of 8, 15, 40, 60, or 80 g/kg, guinea pigs (n = 1 to 6/dose) received doses of 8, 15, 20, 40, 60 or 80 g/kg, and rabbits (n = 1 to 3/dose) received doses of 8, 15, 40, 60, or 80 g/kg. All animals were observed for 10 days post-dosing. Parameters evaluated included mortality, urinalysis, gross pathology, and microscopic pathology (liver, kidneys, spleen, lung). Microscopic pathology was only performed on animals surviving the 10-day observation period. Oral dosing produced deaths in rats and guinea pigs as follows: for rats, one mortality at 60 g/kg on day 5 and one death at 40 g/kg on day 6; and for guinea pigs, one death at 15 g/kg on day 9, one death at 40 g/kg on day 3, and one death at 80 g/kg on day 12. None of the rabbits died. Urinalyses revealed elevated albumin levels for most of the rabbits and almost all of the guinea pigs. Gross and microscopic pathology revealed no adverse effects in rats. In the guinea pigs, pale liver and kidneys was observed in all dose groups, but a dose-response was not apparent. Microscopic pathology revealed: scant or no glycogen storage, congestion and cloudy swelling in the liver; cloudy swelling of the convoluted tubules of the kidney; and no effects in the spleen and lung. In the rabbits, the kidneys were pale and the liver was congested at necropsy. Microscopic examination revealed moderate glycogen storage and congestion in the liver, cloudy swelling, exudate and

	congestion in the kidneys, and minor effects in the lung and spleen. Based on these data, the lowest “fatal oral dose” was 40 g/kg in rats, 15 g/kg in guinea pigs, and 80 g/kg in rabbits.
Data Quality	Valid with restrictions – Klimisch Code 2e
Reference	Smyth, H.F., and Smyth, H.F. 1932. Report to Hercules Powder Company on the examination of [trade name deleted; methyl ester of rosin] for acute toxic effect.

ACUTE TOXICITY – ORAL	
Test substance	
Chemical Name	Methyl ester of rosin
CAS #	68186-14-1
Method	
Method/Guideline followed	Testing was similar to OECD Guideline 401, "Acute Oral Toxicity."
GLP (Y/N)	N (pre-GLP)
Year (Study Performed)	1945
Species	Rat
Strain	Not specified
Route of administration	Oral
Dose levels	47,500 to 63,000 mg/kg
Sex and number/group	6 to 10/group/lot; sex not specified
Frequency of treatment	Single oral gavage
Duration of test	14 day observation post-treatment
Control group (Y/N)	N
Result	
Acute Oral LD_0	Not identified; LD_0 ranged from 47,500 to 63,000 mg/kg
Detailed Summary	Rats (n = 6 to 10/group/material) received a single oral (gavage) dose of one of four lots of rosin methyl ester (CAS #68186-14-1). Doses administered were 47.5, 50, 45, or 63 g/kg and the animals were observed for 14 days. The only parameter evaluated was mortality. The LD_0 (or dose producing no mortality) ranged from 47,500 to 63,000 mg/kg.
Data Quality	Invalid – Klimisch Code 3b
Reference	Shelanski, H.A. 1945. Letter report on acute toxicity of [trade name deleted; methyl ester of rosin]. Smyth Laboratories, Philadelphia, Pennsylvania.

ACUTE TOXICITY – ORAL	
Test substance	
Chemical Name	Methyl ester of rosin
CAS #	68186-14-1
Method	
Method/Guideline followed	Testing was similar to OECD Guideline 401, "Acute Oral Toxicity," except no body weight or gross pathology data were collected.
GLP (Y/N)	N (pre-GLP)
Year (Study Performed)	1948
Species	Rat, Guinea Pig
Strain	Not specified
Route of administration	Oral
Dose levels	30% solution
Sex and number/group	10 rats/group, 10 guinea pigs; sex not specified for either species
Frequency of treatment	Single oral gavage
Duration of test	14 day observation post-treatment
Control group (Y/N)	Y
Result	
Acute Oral LD_{50}	>14,000 mg/kg in rats, 45,000 mg/kg in guinea pigs
Detailed Summary	Both species received a single oral (gavage) dose of methyl ester of rosin (CAS #68186-14-1). Rats (n = 10/group) received a single oral dose of the material as a 30% solution in propylene glycol or sesame oil. Guinea pigs (n = 10/group) received a single oral dose of the material in sesame oil. Control groups were also included. The animals were observed for 14 days post-dosing. Parameters evaluated included mortality and clinical signs. For the rats, the LD_{50} was 14,000 mg/kg for the test substance in the propylene glycol vehicle and greater than 60,000 mg/kg in the sesame oil vehicle. For the guinea pigs, the LD_{50} was 50,000 mg/kg. Administration of the test substance to rats (n = 10/group) as a 30% solution in propylene glycol or sesame oil produced LD_{50} values of 14,000 and 60,000 mg/kg, respectively. Administration of test substance as a 30% solution to guinea pigs (n = 10/group) resulted in an LD_{50} of 45,000 mg/kg.
Data Quality	Invalid – Klimisch Code 3b
Reference	Shelanski, H.A. 1948. Letter report on the acute oral toxicity of [trade name deleted; methyl ester of rosin]. Smyth Laboratories, Philadelphia, Pennsylvania.

ACUTE TOXICITY – ORAL	
Test substance	
Chemical Name	Methyl ester of rosin
CAS #	68186-14-1
Method	
Method/Guideline followed	Testing was similar to OECD Guideline 401, "Acute Oral Toxicity," except no body weight data were collected.
GLP (Y/N)	N
Year (Study Performed)	1972
Species	Rat
Strain	Wistar
Route of administration	Oral
Dose levels	5,000 mg/kg
Sex and number/group	10 males
Frequency of treatment	Single oral gavage
Duration of test	14 day observation post-treatment
Control group (Y/N)	N
Result	
Acute Oral LD_{50}	>5,000 mg/kg
Detailed Summary	Ten male Wistar rats received a single oral dose of 5,000 mg/kg of Compound 72-71 (CAS #68186-14-1) and were observed for 14 days. Parameters evaluated included clinical signs and gross pathology. The rats were lethargic and one death occurred within the first day of dosing. No information on the results of the gross pathology examination was provided. The LD_{50} was greater than 5,000 mg/kg.
Data Quality	Invalid – Klimisch Code 3a
Reference	Moreno, O.M. 1972. Acute oral toxicity in rats of [trade name deleted; methyl ester of rosin]. Toxicological Resources, East Millstone, New Jersey.

REPEAT DOSE TOXICITY	
Test substance	
Chemical Name	Glyercol ester of hydrogenated rosin
CAS #	65997-13-9
Method	
Method/Guideline followed	Test procedure was similar to OECD Test Method 407, "Repeat Dose 28-Day Oral Toxicity Study in Rodents," except no hematology or clinical chemistry data were collected.
Year	1985
GLP (Y/N)	N
Species	Rat
Strain	Sprague-Dawley
Sex	Male, female
Route of Administration	Oral, diet
Exposure Period	28 days
Frequency of Treatment	Daily
Post-exposure observation period	None
Dose Levels	0.2 and 1% (approximately equivalent to 200 and 1000 mg/kg/day)
Control group (Y/N)	Y
Results	
NOAEL:	0.2%, approximately 200 mg/kg/day
Detailed Summary	Sprague-Dawley rats (n = 10/sex/group) were treated with glyercol ester of hydrogenated rosin (CAS #65997-13-9) in the diet at concentrations of 0, 0.2, or 1% for 28 days. The approximate doses were 0, 200, or 1,000 mg/kg/day, based on standard conversion factors (WHO 1990). Parameters evaluated included mortality, morbidity, body weight, food consumption, gross pathology, and microscopic pathology (brain, heart, thymus, tongue, lungs, liver, kidneys, gonads, epididymides, uterus, cervix, prostate, seminal vesicle, spleen, adrenals, thyroid/parathyroid, eye and optic nerve, aorta, pancreas, skin, mammary gland, lymph nodes, trachea, esophagus, stomach, duodenum, jejunum, ileum, cecum, colon, salivary glands, pituitary, spinal cord, sciatic nerve, urinary bladder, muscle, bone and bone marrow, anorectal junction). No deaths or clinical signs were observed in any group. Treated males exhibited similar body weights and body weight gains as control males, but the high-dose females exhibited a significant decrease in body weight throughout the study and a transient decrease in body weight gain during the first two weeks of the study. At 0.2%, a transient decrease in body weight was observed for the females during week 2 only. Food consumption and gross and microscopic pathology were unaffected by treatment.

	Based on these data, the NOAEL was 0.2% (approximately 200 mg/kg/day).
Data Quality	Valid – Klimisch Code 1b
References	Mann, S.W., Robbins, T.L., and Overmyer, S.K. 1985. Twenty-eight-day dietary screening study for [trade name deleted; glyercol ester of hydrogenated rosin]. Project No. 5-131. Adria Laboratories Inc., Plain City, Ohio. World Health Organization (WHO). 1990. Principles for the Toxicological Assessment of Pesticide Residues in Food.

REPEAT DOSE TOXICITY	
Test substance	
Chemical Name	Glycerol ester of rosin
CAS #	8050-31-5
Method	
Method/Guideline followed	Test procedure was consistent with OECD Test Method 408, "Repeat Dose 90-Day Oral Toxicity Study in Rodents"
Year	1989
GLP (Y/N)	Y
Species	Rat
Strain	Charles River
Sex	Male, female
Route of Administration	Oral, diet
Exposure Period	90 days
Frequency of Treatment	Daily
Post-exposure observation period	None
Dose Levels	2000, 5000, and 10000 ppm (approximately equivalent to 136, 339, and 714 mg/kg/day for the males and 156, 402, and 815 mg/kg/day for the females)
Control group (Y/N)	Y
Results	
NOEL:	>10,000 ppm, approximately 800 mg/kg/day
Detailed Summary	Charles River rats (n = 25/sex/group, except for the low dose which was n = 20/sex) were treated with glycerol ester of rosin (CAS #8050-31-5) at dietary concentrations of 0, 2,000, 5,000, or 10,000 ppm for 90 days. Mean compound consumption was calculated to be approximately: 136 to 139 mg/kg/day for males and 156 to 171 mg/kg/day for females ingesting 2,000 ppm; 339 to 340 mg/kg/day for males and 402 to 403 mg/kg/day for females ingesting 5,000 ppm; and 714 mg/kg/day for males and 815 to 831 mg/kg/day for females ingesting 10,000 ppm. Parameters evaluated included mortality, clinical signs, body weight, food consumption, hematology, clinical chemistry, urinalysis, ophthalmology, fecal examination, gross pathology, organ weights (adrenals, brain, heart, kidneys, liver, ovaries, testes), and microscopic pathology (adrenals, aorta, bone with marrow, brain, eyes with optic nerve, gastrointestinal tract, heart, kidneys, liver, lungs, lymph node, ovaries with oviducts, pancreas, peripheral nerve, prostate, salivary gland, seminal vesicles, skeletal muscle, skin with mammary gland, spinal cord, spleen testes with epididymides, thymus, thyroid/parathyroid, tongue, trachea, urinary bladder, uterus with vagina). An interim sacrifice occurred on day 30 at which rats (n = 5/sex/group) from control, mid- and high-dose groups were necropsied.

	The test substance did not affect mortality (100% survival), clinical signs, body weight, body weight gain, food consumption, hematology, clinical chemistry, urinalysis, ophthalmology, fecal observations, gross pathology, organ weights, or microscopic pathology. Based on these data, the NOEL was greater than 10,000 ppm (approximately 800 mg/kg/day).
Data Quality	Valid without restriction – Klimisch Code 1a
Reference	Tompkins, E.C. 1989. Ninety-day dietary study in rats with [trade name deleted; glycerol ester of rosin]. Project No. WIL-87003. WIL Research Laboratories Inc., Ashland, Ohio.

REPEAT DOSE TOXICITY	
Test substance	
Chemical Name	Glycerol ester of rosin
CAS #	8050-31-5
Method	
Method/Guideline followed	Test procedure was consistent with OECD Test Method 408, "Repeat Dose 90-Day Oral Toxicity Study in Rodents"
Year	1991
GLP (Y/N)	Y
Species	Rat
Strain	Charles River Fischer 344
Sex	Male, female
Route of Administration	Oral, diet
Exposure Period	91 days
Frequency of Treatment	Daily
Post-exposure observation period	None
Dose Levels	625, 1250, and 2500 mg/kg/day
Control group (Y/N)	Y
Results	
NOEL:	>2500 mg/kg/day
Detailed Summary	Fischer 344 rats (n = 20/sex/group) were exposed to glycerol ester of rosin (CAS #8050-31-5) in the diet at concentrations to achieve doses of 0, 625, 1250, or 2500 mg/kg/day for 91 days. Parameters evaluated included mortality, clinical signs, body weight, food consumption, ophthalmology, hematology, clinical chemistry, gross pathology, organ weights (adrenals, brain, cecum, heart, kidneys, liver, ovaries, testes, thymus), and microscopic pathology (adrenals, aorta, bone, bone marrow, brain, eye with optic nerve, gastrointestinal tract, ovaries, testes with epididymis, heart, kidneys, liver, lung, lymph nodes, mammary gland, pancreas, pituitary, prostate with seminal vesicle, salivary gland, sciatic nerve, skeletal muscle, skin, spinal cord, spleen, thymus, thyroid/parathyroid, trachea, urinary bladder, uterus). No deaths occurred and no clinical signs were reported. Slight changes in body weight were reported in the females at 1,250 and 2,500 mg/kg/day (during the latter weeks) and in the males at 2,500 mg/kg/day (during week 8). Food consumption was significantly increased in the high-dose males and females. Some increases were reported in the 1,250 mg/kg/day males. No treatment-related effects were reported on ophthalmology, hematology, clinical chemistry, gross pathology, or microscopic pathology. Some organ weight increases were reported, but due to a lack of concomitant pathological changes they were not considered to be treatment-related. The authors concluded

	that the NOAEL was 2,500 mg/kg/day.
Data Quality	Valid without restriction – Klimisch Code 1a
Reference	Blair, M. 1991. Thirteen-week dietary toxicity study in rats. Study No. 548-007. International Research and Development Corporation, Mattawan, Michigan.

REPEAT DOSE TOXICITY	
Test substance	
Chemical Name	Glycerol ester of hydrogenated rosin
CAS #	65997-13-9
Method	
Method/Guideline followed	Test procedure was consistent with OECD Test Method 408, "Repeat Dose 90-Day Oral Toxicity Study in Rodents"
Year	1987
GLP (Y/N)	Y
Species	Rat
Strain	Sprague-Dawley COBS
Sex	Male, female
Route of Administration	Oral, diet
Exposure Period	90 days
Frequency of Treatment	Daily
Post-exposure observation period	None
Dose Levels	2000, 5000, and 10000 ppm (approximately equivalent to 200, 500, and 1,000 mg/kg/day)
Control group (Y/N)	Y
Results	
NOEL:	>10000 ppm, approximately 1000 mg/kg/day
Detailed Summary	Sprague Dawley rats (n = 25/sex/group, except for the low dose which was n = 20/sex) were treated with glycerol ester of hydrogenated rosin (CAS #65997-13-9) in the diet at concentrations of 0, 2000, 5000, or 10000 ppm for 90 days. The approximate doses were 0, 200, 500 or 1,000 mg/kg/day, based on standard conversion factors (WHO 1990). Parameters evaluated included mortality, clinical signs, body weight, food consumption, hematology, clinical chemistry, urinalysis, ophthalmology, fecal parameters, gross pathology, organ weights, and microscopic pathology (adrenals, aorta, bone with marrow, brain, eyes with optic nerve, esophagus, stomach, duodenum, jejunum, ileum, cecum, colon, rectum, heart, kidneys, liver, lungs, lymph node, ovary, pancreas, peripheral nerve, pituitary, prostate, salivary gland, seminal vesicles, skeletal muscle, skin with mammary gland, spinal cord, spleen, testes with epidydimides, thymus, thyroids, tongue, trachea, urinary bladder, uterus with vagina). At 30 days, an interim sacrifice occurred (n = 5/sex/group) for the control, mid- and high-dose groups. One control male died during week 11 due to a cerebral hemorrhage. All other animals survived and no clinical signs were observed. No treatment-related effects were reported on body weight, body weight gain, food consumption, hematology, clinical chemistry, urinalysis, ophthalmology, fecal parameters, gross pathology, organ

	weights, or microscopic pathology. Based on these data, the NOEL was 10,000 ppm (approximately 1,000 mg/kg/day).
Data Quality	Valid without restriction – Klimisch Code 1a
References	Laveglia, J. 1987. Ninety-day dietary study in rats with [trade name deleted; glycerol ester of hydrogenated rosin]. Project No. WIL-87001. WIL Research Laboratories, Inc., Ashland, Ohio. World Health Organization (WHO). 1990. Principles for the Toxicological Assessment of Pesticide Residues in Food.

REPEAT DOSE TOXICITY	
Test substance	
Chemical Name	Pentaerythritol ester of rosin
CAS #	8050-26-8
Method	
Method/Guideline followed	Test procedure was similar to OECD Test Method 408, "Repeat Dose 90-Day Oral Toxicity Study in Rodents," except limited hematology data and no clinical chemistry data were collected.
Year	1960
GLP (Y/N)	N (pre-GLP)
Species	Rat
Strain	Sprague-Dawley
Sex	Male, female
Route of Administration	Oral, diet
Exposure Period	90 days
Frequency of Treatment	Daily
Post-exposure observation period	None
Dose Levels	0.01, 0.05, 0.2, 1, and 5% (approximately equivalent to 10, 50, 200, 1000 and 5,000 mg/kg/day)
Control group (Y/N)	Y
Results	
NOEL:	1%, approximately 1000 mg/kg/day
Detailed Summary	Sprague-Dawley rats (n = 10/sex/group) were treated with pentaerythritol ester of rosin (CAS #8050-26-8) at dietary concentrations of 0, 0.01, 0.05, 0.2, 1, or 5% for 90 days. The approximate doses were 0, 10, 50, 200, 1,000, or 5,000 mg/kg/day, based on standard conversion factors (WHO 1990). Parameters evaluated included mortality, clinical signs, body weight, body weight gain, food utilization, food consumption, hematology, urinalysis, gross pathology, organ weights (brain, heart, liver, kidneys, spleen, testes, ovaries), and microscopic pathology (brain, liver, spleen, stomach, small intestine, colon, pancreas, kidneys, urinary bladder, adrenals, gonads, thyroid, parathyroid, lymph nodes, heart, lungs, bone marrow, muscle, prostate, uterus). One animal from the 0.05, 0.2, and 1% groups died on days 42, 48, and 42, respectively. Two animals from the 5% group died on days 53 and 58. No treatment trend was observed. Treatment did not affect body weight, body weight gain, clinical signs, hematology, urinalysis, or gross pathology. Food consumption was decreased at 5%, but food utilization (grams of weight gained/grams of food consumed) was unaffected. This suggests that the decrease in consumption was related to palatability. Absolute and relative liver weights were significantly

	increased in the high-dose males and females, however, no changes were observed at histopathology. Based on these data, the NOEL is 1% (approximately 1,000 mg/kg/day).
Data Quality	Valid without restriction – Klimisch Code 1b
References	Calandra, J.C. 1960. Ninety-day subacute oral toxicity of [trade name deleted; pentaerythritol ester of rosin]. Industrial Bio-Test Laboratories, Inc., Northbrook, Illinois. World Health Organization (WHO). 1990. Principles for the Toxicological Assessment of Pesticide Residues in Food.

REPEAT DOSE TOXICITY	
Test substance	
Chemical Name	Pentaerythritol ester of rosin
CAS #	8050-26-8
Method	
Method/Guideline followed	Test procedure was similar to OECD Test Method 408, "Repeat Dose 90-Day Oral Toxicity Study in Rodents," except limited hematology data and no clinical chemistry data were collected.
Year	1960
GLP (Y/N)	N (pre-GLP)
Species	Rat
Strain	Sprague-Dawley
Sex	Male, female
Route of Administration	Oral, diet
Exposure Period	90 days
Frequency of Treatment	Daily
Post-exposure observation period	None
Dose Levels	0.01, 0.05, 0.2, 1, and 5% (approximately equivalent to 10, 50, 200, 1000 and 5,000 mg/kg/day)
Control group (Y/N)	Y
Results	
NOEL:	1%, approximately 1000 mg/kg/day
Detailed Summary	Sprague-Dawley rats (n = 10/sex/group) were treated with pentaerythritol ester of rosin (CAS #8050-26-8) at dietary concentrations of 0, 0.01, 0.05, 0.2, 1, or 5% for 90 days. The approximate doses were 0, 10, 50, 200, 1,000, or 5,000 mg/kg/day, based on standard conversion factors (WHO 1990). Parameters evaluated included mortality, clinical signs, body weight, body weight gain, food utilization, food consumption, hematology, urinalysis, gross pathology, organ weights (brain, heart, liver, kidneys, spleen, testes, ovaries), and microscopic pathology (brain, liver, spleen, stomach, small intestine, colon, pancreas, kidneys, urinary bladder, adrenals, gonads, thyroid, parathyroid, lymph nodes, heart, lungs, bone marrow, muscle, prostate, uterus). No animals died and no clinical signs were observed. Treatment did not affect body weight, body weight gain, hematology, or urinalysis. Food consumption was decreased at 5% and food utilization was increased at this concentration. The higher corn oil content at this dose level may explain these findings. At necropsy, the testes in the 5% males were diminished in size. In addition, the absolute and relative testes weights were statistically significantly decreased. Histopathology revealed decreased numbers of developing spermatozoa, maturation

	arrest of spermatozoa, and strange morphological forms in the high-dose males. Based on these data, the NOEL is 1% (approximately 1,000 mg/kg/day).
Data Quality	Valid without restriction – Klimisch Code 1b
References	Calandra, J.C. 1960. Ninety-day subacute oral toxicity of [trade name deleted; pentaerythritol ester of rosin]. Industrial Bio-Test Laboratories, Inc., Northbrook, Illinois. World Health Organization (WHO). 1990. Principles for the Toxicological Assessment of Pesticide Residues in Food.

REPEAT DOSE TOXICITY	
Test substance	
Chemical Name	Glycerol ester of rosin
CAS #	8050-31-5
Method	
Method/Guideline followed	Test procedure was similar to OECD Test Method 408, "Repeat Dose 90-Day Oral Toxicity Study in Rodents."
Year	1982
GLP (Y/N)	N
Species	Rat
Strain	Sprague-Dawley
Sex	Male, female
Route of Administration	Oral, diet
Exposure Period	90 days
Frequency of Treatment	Daily
Post-exposure observation period	None
Dose Levels	0.2, 1, and 5% (approximately equivalent to 200, 1000 and 5,000 mg/kg/day)
Control group (Y/N)	Y
Results	
NOAEL:	1%, approximately 1000 mg/kg/day
Detailed Summary	Sprague-Dawley rats (n = 15/sex/group) were treated with glycerol ester of rosin (CAS #8050-31-5) at dietary concentrations of 0, 0.2, 1, or 5% for 90 days. The approximate doses were 0, 200, 1,000, or 5,000 mg/kg/day, based on standard conversion factors (WHO 1990). Parameters evaluated included mortality, clinical signs, body weight, food consumption, hematology, clinical chemistry, urinalysis, fecal examination, gross pathology, organ weights (adrenals, brain, ovaries, thyroid/parathyroid, heart, kidneys, liver, spleen, testes), and microscopic pathology (adrenals, anorectal junction, aorta, bone and bone marrow, cecum, cervix, colon, duodenum, epididymides, lymph node, ovaries, pancreas, parathyroid/thyroid, pituitary, prostate, salivary glands, sciatic nerve, seminal vesicles, skeletal muscle, esophagus, eye and optic nerve, heart, ileum, jejunum, kidneys, liver, lung, mammary gland, skin, spinal cord, spleen, stomach, testes, thymus, tongue, trachea, urinary bladder, uterus). One high-dose male died on day 89 exhibiting a swollen, bleeding nose and difficulty breathing one day prior to death and epistaxis three hours prior to death. No clinical signs were observed in any dose group and no other deaths were reported. Treatment did not affect body weight, hematology, clinical chemistry, urinalysis, or fecal examination. Food consumption was statistically

	significantly decreased in the high-dose males during weeks one through five and 13 and in the high-dose females during weeks one through three, five and nine. These decreases were determined to be related to the palatability of the test material. Dose-related, statistically significant increases were reported in absolute and relative liver weights in the high-dose females, and in relative liver weight in the high-dose males and in the mid-dose males and females. Histopathology revealed very slight to slight periportal hepatocytic vacuolation in the high-dose females only. No other histopathological changes were noted. Based on these data, the NOAEL was 1% (approximately 1,000 mg/kg/day).
Data Quality	Valid without restriction – Klimisch Code 1b
References	Mann, S.W., Iuliucci, J.D., and Schlicht, M.P. 1982. Three month toxicity study on [trade name deleted; glycerol ester of rosin] given orally (diet) to rats. Project No. 5-073. Adria Laboratories Inc., Plain City, Ohio. World Health Organization (WHO). 1990. Principles for the Toxicological Assessment of Pesticide Residues in Food.

REPEAT DOSE TOXICITY	
Test substance	
Chemical Name	Glycerol ester of rosin
CAS #	8050-31-5
Method	
Method/Guideline followed	Test procedure was similar to OECD Test Method 408, "Repeat Dose 90-Day Oral Toxicity Study in Rodents," except limited hematology data and no clinical chemistry data were collected.
Year	1960
GLP (Y/N)	N (pre-GLP)
Species	Rat
Strain	Sprague-Dawley
Sex	Male, female
Route of Administration	Oral, diet
Exposure Period	90 days
Frequency of Treatment	Daily
Post-exposure observation period	None
Dose Levels	0.01, 0.05, 0.2, 1, and 5% (approximately equivalent to 10, 50, 200, 1000 and 5,000 mg/kg/day)
Control group (Y/N)	Y
Results	
NOEL:	1%, approximately 1000 mg/kg/day
Detailed Summary	Sprague-Dawley rats (n = 10/sex/group) were treated with glycerol ester of rosin (CAS #8050-31-5) at dietary concentrations of 0, 0.01, 0.05, 0.2, 1, or 5% for 90 days. The approximate doses were 0, 10, 50, 200, 1,000, or 5,000 mg/kg/day, based on standard conversion factors (WHO 1990). Parameters evaluated included mortality, clinical signs, body weight, body weight gain, food consumption, food utilization, hematology, urinalysis, gross pathology, organ weights (brain, heart, liver, kidneys, spleen, testes, ovaries), and microscopic pathology (brain, liver, spleen, stomach, small intestine, colon, pancreas, kidneys, urinary bladder, adrenals, gonads, thyroid, parathyroid, lymph nodes, heart, lungs, bone marrow, muscle, prostate, uterus). No deaths occurred and no adverse clinical signs were noted. Body weight and body weight gain were not affected by treatment. In the high-dose group, food consumption was slightly decreased, but food utilization (grams of body weight gained/grams of food consumed) was increased. The higher utilization values were related to the higher caloric content of the 5% dose group. No treatment related effects on hematology, urinalysis, gross pathology or organ weights were reported. Histopathology did not reveal any adverse effects. Based on these data,

	the NOEL was 1% (approximately 1,000 mg/kg/day).
Data Quality	Valid without restriction – Klimisch Code 1b
References	Calandra, J.C. 1960. Ninety-day subacute oral toxicity of [trade name deleted; glycerol ester of rosin]. Industrial Bio-Test Laboratories, Inc., Northbrook, Illinois. World Health Organization (WHO). 1990. Principles for the Toxicological Assessment of Pesticide Residues in Food.

REPEAT DOSE TOXICITY	
Test substance	
Chemical Name	Glycerol ester of hydrogenated rosin
CAS #	65997-13-9
Method	
Method/Guideline followed	Test procedure was similar to OECD Test Method 408, "Repeat Dose 90-Day Oral Toxicity Study in Rodents," except limited hematology data and no clinical chemistry data were collected.
Year	1967
GLP (Y/N)	N (pre-GLP)
Species	Rat
Strain	Charles River
Sex	Male, female
Route of Administration	Oral, diet
Exposure Period	90 days
Frequency of Treatment	Daily
Post-exposure observation period	None
Dose Levels	0.2, 1, and 5% (approximately equivalent to 200, 1000 and 5,000 mg/kg/day)
Control group (Y/N)	Y
Results	
NOEL:	1%, approximately 1000 mg/kg/day
Detailed Summary	Charles River rats (n = 10/sex/group) were exposed to glycerol ester of hydrogenated rosin (CAS #65997-13-9) in the diet at concentrations of 0, 0.2, 1, or 5% for 90 days. The approximate doses were 0, 200, 1,000 or 5000 mg/kg/day, based on standard conversion factors (WHO 1990). Parameters evaluated included mortality, clinical signs, body weight, body weight gain, food consumption, hematology, urinalysis, gross pathology, organ weights (liver, kidneys, spleen, gonads, heart, thyroids, adrenals, brain), and microscopic pathology (esophagus, stomach, small intestine, cecum, colon, liver, kidney, spleen, pancreas, urinary bladder, pituitary gland, adrenal gland, testis, ovary, thyroid gland, parathyroid gland, heart, lung, lymph node, bone marrow, skeletal muscle, uterus, seminal vesicle, trachea, prostate, salivary gland, eye, optic nerve, peripheral nerve, spinal cord, brain). One control male died on day 78, but no other deaths occurred and no clinical signs were noted. No treatment-related effects were reported on body weight, body weight gain, hematology, urinalysis, gross pathology, organ weights, or microscopic pathology. High-dose male and female rats exhibited a decrease in food consumption throughout the study. It was suggested that this was due to the high corn oil content in the 5% diet. Based on these

	data, the NOEL was 1% (approximately 1,000 mg/kg/day).
Data Quality	Valid without restriction – Klimisch Code 1b
References	Calandra, J.C. 1967. Ninety-day subacute oral toxicity of [trade name deleted; glycerol ester of hydrogenated rosin] – albino rats. IBT No. B 4862. Industrial Bio-Test Laboratories, Inc., Northbrook, Illinois. World Health Organization (WHO). 1990. Principles for the Toxicological Assessment of Pesticide Residues in Food.

REPEAT DOSE TOXICITY	
Test substance	
Chemical Name	Pentaerythritol ester of rosin
CAS #	8050-26-8
Method	
Method/Guideline followed	Test procedure was similar to OECD Test Method 452, "Chronic Toxicity Studies," except only one dose was administered, and limited hematology data and no clinical chemistry or ophthalmology data were collected.
Year	1962
GLP (Y/N)	N (pre-GLP)
Species	Rat
Strain	Sprague-Dawley
Sex	Male, female
Route of Administration	Oral, diet
Exposure Period	Two years
Frequency of Treatment	Daily
Post-exposure observation period	None
Dose Levels	0.05% (approximately equivalent to 50 mg/kg/day)
Control group (Y/N)	Y
Results	
NOAEL:	0.05%, approximately 50 mg/kg/day
Detailed Summary	Sprague-Dawley rats (n = 30/sex/group) were exposed to pentaerythritol ester of rosin (CAS #8050-26-8) in the diet at concentrations of 0, 0 or 0.05% for two years (i.e., two control groups). The approximate doses were 0 or 50 mg/kg/day, based on standard conversion factors (WHO 1990). Parameters evaluated included mortality, clinical signs, body weight, body weight gain, food utilization, food consumption, hematology, urinalysis, gross pathology, tumor incidence, organ weights (liver, kidneys, spleen, gonads, heart, brain, thyroid, adrenals), and microscopic pathology (heart, lung, trachea, liver, pancreas, stomach, small intestine, colon, spleen, lymph node, kidney, urinary bladder, testis, ovary, prostate, uterus, pituitary, adrenal gland, salivary gland, thyroid gland, parathyroid gland, skeletal muscle, bone marrow, brain). At 12 months, an interim sacrifice occurred (n = 5/sex/group). The number of animals dying or sacrificed moribund (from tumors) was: 12 males and 6 females in the first control group; 7 males and 9 females in the second control group; and 9 males and 10 females in the 0.05% group. No treatment effect was evident and the deaths were largely related to respiratory illness. Treatment did not affect body weight, body weight gain, food consumption, food utilization, hematology, urinalysis, gross pathology, organ weights or microscopic pathology. The number of tumor

	bearing animals was: 0 males and 5 females in the first control group; 0 males and 9 females in the second control group; and 2 males and 7 females in the 0.05% group. In all groups, the tumors were primarily subcutaneous fibroadenomas or adenofibromas. No treatment-related effect was apparent.
Data Quality	Valid with restriction – Klimisch Code 2e
References	Kay, J.H. 1962. Two-year chronic oral toxicity of [trade name deleted; pentaerythritol ester of rosin] – albino rats. Industrial Bio-Test Laboratories, Inc., Northbrook, Illinois. World Health Organization (WHO). 1990. Principles for the Toxicological Assessment of Pesticide Residues in Food.

IN VITRO GENETIC TOXICITY	
Test substance	
Chemical Name	Glycerol ester of rosin
CAS #	8050-31-5
Method	
Method/Guideline followed	Test was consistent with OECD Test Method 471, "Bacterial Reverse Mutation Test"
Year	1988
GLP (Y/N)	Y
System of testing	*S. typhimurium* strains TA98, TA100, TA1535, TA1537, TA1538
Concentration	2.5 to 500 μg/plate
Metabolic activation	With and without
Results	Non-mutagenic
Detailed Summary	Glycerol ester of rosin (CAS #8050-31-5) was incubated with five strains of *Salmonella typhimurium* (TA100, TA98, TA1538, TA1537, TA1535) in the presence and absence of a metabolic activating system (S9 mix). In the definitive assay, concentrations ranging from 2.5 to 500 μg/plate were tested. The study was conducted in duplicate. Both positive and negative controls were employed. No increase in the number of revertant colonies was measured in either the presence or absence of S9 mix. Glycerol ester of rosin was not mutagenic in this assay.
Data Quality	Valid without restriction – Klimisch Code 1a
Reference	Jagannath, D.R. 1988. Mutagenicity test on [trade name deleted; glycerol ester of rosin] in the Ames Salmonella/microsome reverse mutation assay. HLA Study No. 10349-0-401. Hazleton Laboratories America, Inc., Kensington, Maryland.

IN VITRO GENETIC TOXICITY	
Test substance	
Chemical Name	Glycerol ester of rosin
CAS #	8050-31-5
Method	
Method/Guideline followed	Test was consistent with OECD Test Method 473, "In Vitro Mammalian Cytogenetic Test"
Year	1988
GLP (Y/N)	Y
System of testing	Chinese hamster ovary cells
Concentration	50.7 to 507 μg/mL
Metabolic activation	With and without
Results	Non-mutagenic
Detailed Summary	Glycerol ester of rosin (CAS #8050-31-5) was incubated with Chinese hamster ovary (CHO) cells in the presence and absence of a metabolic activating system (S9 mix). In the nonactivation assay, cells were treated with the test article for 7.3 hours, washed and treated with Colcemid for 2.5 hours. In the activation assay, cells were treated with the test article for 2 hours, washed, and treated with Colcemid for the final 2.5 hours of the ten-hour incubation period. After this treatment time, the cells were prepared for cyogenetic analysis; 100 cells per culture were examined. In the definitive assay, concentrations ranging from 50.7 to 507 μg/mL were tested. The study was conducted in duplicate. Positive controls were employed. No increase in the number of chromosomally aberrant cells was measured in either the presence or absence of S9 mix. Glycerol ester of rosin was not mutagenic in this assay.
Data Quality	Valid without restriction – Klimisch Code 1a
Reference	Murli, H. 1988. Mutagenicity test on [trade name deleted; glycerol ester of rosin] in an in vitro cytogenetic assay measuring chromosomal aberration frequencies in Chinese hamster ovary (CHO) cells. HLA Study No. 10349-0-437. Hazleton Laboratories America, Inc., Kensington, Maryland.

IN VITRO GENETIC TOXICITY	
Test substance	
Chemical Name	Glycerol ester of rosin
CAS #	8050-31-5
Method	
Method/Guideline followed	Test was consistent with OECD Test Method 482, "DNA Damage and Repair, Unscheduled DNA Synthesis in Mammalian Cells in Vitro"
Year	1988
GLP (Y/N)	Y
System of testing	Rat primary hepatocytes
Concentration	5.08 to 102 μg/mL
Metabolic activation	With and without
Results	Non-mutagenic
Detailed Summary	Glycerol ester of rosin (CAS #8050-31-5) was incubated with rat primary hepatocytes. The hepatocytes were allowed to attach to the culture dish for 1.5 to 2 hours after which cells were exposed to the test article along with ^{3}H-thymidine for 18 to 19 hours. The cultures were washed and cell counts were taken. The labeled cells were fixed, dried, and developed for microscopic examination. One hundred fifty cells from each treatment group were examined. Concentrations ranging from 5.08 to 102 μg/mL were examined for unscheduled DNA synthesis. Both positive and negative controls were used. No evidence of unscheduled DNA synthesis was observed. Glycerol ester of rosin was negative in this assay.
Data Quality	Valid without restriction – Klimisch Code 1a
Reference	Cifone, M.A. 1988. Mutagenicity test on [trade name deleted; glycerol ester of rosin] in the rat primary hepatocyte unscheduled DNA synthesis assay. HLA Study No. 10349-0-447. Hazleton Laboratories America, Inc., Kensington, Maryland.